NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by 1st submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Due to time restraints, the Secretary of State's Office will no longer edit the text of proposed rules. We will continue to make numbering and labeling changes as necessary.

Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for adoption, amendment, or repeal of any rule. A.R.S. §§ 41-1013 and 41-1022.

NOTICE OF PROPOSED RULEMAKING

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

PREAMBLE

1. **Sections Affected** — **Rulemaking Action**
   R4-23-110 — Amend
   R4-23-402 — Amend

2. **The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):**
   Authorizing statute: A.R.S. § 32-1904(A)(1)

   Implementing statute: A.R.S. § 32-1904(B)(5)

3. **The name and address of agency personnel with whom persons may communicate regarding the rule:**
   Name: Dean Wright, Compliance Officer

   Address: Board of Pharmacy
   5060 North 19th Avenue, Suite 101
   Phoenix, Arizona 85015

   Telephone: (602) 255-5125, Ext. 131

   Fax: (602) 255-5740

4. **An explanation of the rule, including the agency's reason for initiating the rule:**
   This rule was initiated at the request of the Arizona Pharmacy Association. The Arizona Pharmacy Association represents pharmacies and pharmacists in the state of Arizona. In the fall of 1994, a committee consisting of members from the Arizona Pharmacy Association and the Board staff worked together to identify possible changes in existing rule. Some of those changes are formalized in these proposed rules.

   The rule amends the definitions of "prepackaged drug" and "mediated instruction" to improve clarity and conciseness. The rule also incorporates the use of "graduate intern". Recent statutory changes created the "graduate intern" designation and the rule incorporates the term where applicable. The rule addresses format and style changes necessary under the current administrative procedures act and other necessary language changes to provide a clear, concise, and understandable document.

   The rule makes changes to R4-23-402 that address the professional practice duties of pharmacists, graduate interns, and pharmacy interns. Specifically, the rule changes the heading to include graduate intern and adds language that:

   A. Requires a pharmacist to maintain a patient profile containing specific patient information,

   B. Addresses oral consultation including:

      1. Minimum requirements for oral consultation;

      2. Additional items of oral consultation that allow the use of professional judgement; and

      3. A refusal of consultation including participants, conditions, and documentation;

   C. Clearly defines the written or printed patient drug information that shall accompany a prescription delivered to a patient; and

D. Allows the use of new technology in recordkeeping and increases accountability.

The Board believes that adoption of these rules will benefit the public health and safety by establishing clear standards of pharmacy practice intended to promote the delivery of pharmaceutical care. Specifically, the rule addresses the duties of pharmacist, graduate intern, and pharmacy intern. The Board further believes that specific regulation and enforcement are necessary to regulate and control the rapidly evolving role of pharmacists in a dynamic healthcare system.

5. **A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**

Not applicable.

6. **The preliminary summary of the economic, small business, and consumer impact:**

The rule increases protection of public health and safety by establishing clear standards of pharmacy practice intended to promote the delivery of pharmaceutical care. By utilizing patient profiles, verifying allergies and drug incompatibilities, monitoring drug usage, identifying potential and actual drug-related problems, resolving actual drug-related problems, and preventing potential drug-related problems, the pharmacist can help the patient achieve the outcome the physician intended through drug therapy. Several recently published national studies have provided estimates of the cost of drug-related problems. One such study, "Drug-related Morbidity and Mortality and the Economic Impact of Pharmaceutical Care" by Jeffrey A. Johnson and J. Lyle Bootman published in the American Journal of Health-System Pharmacists, Vol. 54, March 1, 1997, estimated the cost figure at 76.6 billion dollars annually. This study only dealt with unresolved or unrecognized drug-related problems in the U.S. ambulatory care population. Another study, "The Health Care Cost of Drug-Related Morbidity and Mortality in Nursing Facilities" by J. Lyle Bootman, Ph.D., LTC Donald L. Harrison, Ph.D., and Emily Cox, Ph.D. published in the Archives of Internal Medicine, Vol. 157, October 13, 1997, estimated the cost of drug-related problems in nursing homes at 7.6 billion dollars annually. Another study estimated the cost of drug-related problems in institutional settings at 15 to 20 billion dollars annually. The estimated total annual cost of drug-related problems in the U.S. comes to almost 100 billion dollars. These figures are for the entire United States population. By extrapolation just based on population, the estimated cost of drug-related problems in Arizona is over 1 billion dollars annually. Obviously, the establishment of pharmacy practice standards intended to promote pharmaceutical care will benefit everyone by lowering the cost of health care. The rule deals with standards of practice and benefits the Board of Pharmacy by promoting consistent compliance. Arizona pharmacies and pharmacists benefit because the rule is concise and compliance standards are crystal clear.

Less than 2% of Arizona pharmacies do not have a patient profile system as required by the proposed rulemaking. The costs required to comply with the proposed rulemaking are minimal. These costs relate directly to the use of a patient profile system. The least expensive manual patient profile system would cost less than a hundred dollars annually. Of course, to use a more efficient computer-based patient profile system would cost several thousand dollars initially and have annual maintenance costs of several hundred dollars. However, the proposed rulemaking does not require a computer-based system and anything above the minimal manual system would be at the discretion of the business owner.

7. **The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:**

Name: Dean Wright, Compliance Officer

Address: Board of Pharmacy
5060 North 19th Avenue, Suite 101
Phoenix, Arizona 85015

Telephone: (602) 255-5125, Ext. 131

Fax: (602) 255-5740

8. **The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:**

Comments may be written or presented orally. Written comments must be received by 5 p.m., Monday, April 13, 1998. An oral proceeding on the proposed rule is scheduled for:

Date: April 13, 1998

Time: 10 a.m.

Location: Board of Pharmacy
5060 North 19th Avenue, Suite 101
Phoenix, Arizona 85015

Nature: A person may request information about the oral proceeding by contacting the person listed in question #7.

9. **Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**

Not applicable.

10. **Incorporations by reference and their location in the rules:**

None.

11. The full text of the rules follows:

TITLE 4. PROFESSIONS AND OCCUPATIONS

CHAPTER 23. BOARD OF PHARMACY

ARTICLE 1. ADMINISTRATION

Section
R4-23-110. Definitions

ARTICLE 4. PROFESSIONAL PRACTICES

Section
R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern

ARTICLE 1. ADMINISTRATION

R4-23-110. Definitions

"Active ingredient" means any component which is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the body of man or other animals. The term shall include those components which may undergo chemical change in the manufacture of the drug and be present in the finished drug products in a modified form intended to furnish the specified activity or effect.

"Authentication of product history" means identifying the purchasing source, the ultimate fate, and any intermediate handling of any component of a radiopharmaceutical or other drug.

"AZPLEX" means Arizona pharmacy law examination written and administered by the Board Staff or a Board-approved national pharmacy law examination written and administered in cooperation with NABP.

"Batch" means a specific quantity of drug that has uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

"Beyond-use date" means a date determined by a pharmacist and placed on a prescription label at the time of dispensing intended to indicate a time beyond which the contents of the prescription are not recommended to be used.

"Biological safety cabinet" means a containment unit suitable for the preparation of low to moderate risk agents where there is a need for protection of the product, personnel and environment, consistent with National Sanitation Foundation (NSF) standards, published in the National Sanitation Foundation Standard 49, Class II (Laminar Flow) Biohazard Cabinetry, Revised June 1987 edition, incorporated herein by reference and on file with the Office of the Secretary of State.

"Class 100 environment" means an atmospheric environment in compliance with the Federal Standard 209 Clean Room and Work Station Requirements: Controlled Environment, publication FED-STD-209D, June 15, 1988 edition which includes January 28, 1991 changes, incorporated herein by reference and on file with the Office of the Secretary of State.

"Community pharmacy" means any place under the direct supervision of a pharmacist where the practice of pharmacy occurs or where prescription orders are compounded and dispensed other than a hospital pharmacy or a limited service pharmacy.

"Component" means any ingredient intended for use in compounding or manufacturing drugs in dosage form, including an ingredient that may not appear in the finished product.

"Container" means

A receptacle, as described in the official compendium or the federal act, that is used in manufacturing or compounding a drug or in distributing, supplying, or dispensing the finished dosage form of a drug; or

A metal receptacle that is designed to contain liquefied or vaporized compressed medical gas and that is used in manufacturing, transfilling, distributing, supplying, or dispensing a compressed medical gas.

"Correctional facility" has the same meaning as set forth in A.R.S. §§ 13-2501 and 31-341.

"Current good compounding practices" means the minimum standards for methods used in, and facilities or controls used for, compounding a drug to ensure that the drug has the identity and strength and meets the quality and purity characteristics it purports or is represented to possess.

"Current good manufacturing practice" means the minimum standard for methods to be used in, and facilities or controls to be used for manufacturing, processing, packing, or holding a drug to ensure that the drug meets the requirements of the federal act as to safety, and has the identity and strength and meets the quality and purity characteristics it purports or is represented to possess.

"Cytotoxic" means a pharmaceutical that has the capability of killing living cells.

"Day" means a calendar day unless otherwise specified.

"Delinquent license" means a pharmacist or intern license that is suspended for failure to renew and pay all required fees on or before the date the renewal is due.

"Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

"Extreme emergency" means the occurrence of a fire, water leak, electrical failure, public disaster or other catastrophe constituting an imminent threat of physical harm to pharmacy personnel or patrons.

"FDA" means the Food and Drug Administration, a federal agency within the United States Department of Health and Human Services, established to set safety and quality standards for foods, drugs, cosmetics, and other consumer products.

"First aid stations" means units within a business or industrial organization which are limited to, as the name implies, first aid treatment of injuries incurred in association with the business function.

"Inactive ingredient" means any component other than an "active ingredient" present in a drug.

"Industrial medical stations" means units where drugs are stored, established within businesses and industrial organizations.

"Internal test assessment" means, but is not limited to, performing quality assurance procedures necessary to ensure the integrity of the test.

"Limited-service correctional pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, is located in a correctional facility, and engages in the compounding, production, dispensing, and distribution of drugs.

"Limited-service mail-order pharmacy" means a limited-service pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board pursuant to A.R.S. § 32-1931, and dispenses a majority of its prescription medication or prescription-only devices by mailing or delivering the prescription medication or prescription-only device to an individual by the United States mail, a common or contract carrier, or a delivery service.

"Limited-service nuclear pharmacy" means a limited service pharmacy, as defined in A.R.S. § 32-1901, that holds a current permit issued by the Board under A.R.S. § 32-1931, and provides radiopharmaceutical services.

"Limited-service pharmacy permittee" means a person who has applied for and obtained a limited-service pharmacy permit in compliance with A.R.S. §§ 32-1929, 32-1930, 32-1931, and A.A.C. R4-23-606.

"Long-term care consultant pharmacist" means a pharmacist providing consulting services to a long term care facility.

"Lot" means a batch or any portion of a batch of a drug or in the case of a drug produced by a continuous process, an amount of drug produced in a unit of time or quantity in a manner that assures it uniformity, and in either case which is identified by a distinctive lot number and has uniform character and quality with specified limits.

"Lot number" or "control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the compounding or manufacturing, control, packaging, and distribution of a batch or lot of a drug can be determined.

"Materials approval unit" means any organizational element having the authority and responsibility to approve or reject components, in-process materials, packaging components and final products.

"Mediated instruction" means learning transmitted via intermediate mechanisms such as audio and/or visual tape telephone transmission~~, etc~~.

"NABP" means National Association of Boards of Pharmacy.

"NABPLEX" means National Association of Boards of Pharmacy Licensure Examination.

"NAPLEX" means North American Pharmacist Licensure Examination.

"Occupational Medicine" or "Industrial Medicine" means the field of medicine dealing with the medical problems associated with persons employed in any occupation.

"Outpatient" or "Outpatient setting" means a person that receives medical treatment as result of not being a residential patient in a health care institution, or a location where medical treatment is provided to patients not required to be overnight residents of the facility.

"Patient profile" means a readily retrievable, centrally located information record which contains, but is not limited to: patient demographics, allergies, and medication profile.

"Pharmaceutical care" means the provision of drug therapy and other pharmaceutical patient care services intended to achieve outcomes, related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, or arresting or slowing of a disease process, by identifying potential and actual drug-related problems, resolving actual drug-related problems, and preventing potential drug-related problems.

"Pharmacy law continuing education" means a continuing education activity that addresses practice issues related to state or federal pharmacy statutes, rules or regulations, offered by an Approved Provider.

"Prepackaged drug" means a drug that~~which~~ is packaged~~, ordinarily~~ in a frequently prescribed quantity~~quantities~~, labeled~~,~~ in compliance with A.R.S. §§ 32-1967 and 32-1968, stored, ~~for storage~~ and subsequently dispensed ~~dispensing~~ by a pharmacist~~,~~ or a graduate intern or pharmacy intern under the supervision of a pharmacist, who ~~at that time~~ verifies at the time of dispensing that the drug ~~it~~ is properly labeled for the patient.

"Provider pharmacist" means the pharmacist who supplies medication to a long term care facility and maintains medication profiles.

"Radiopharmaceutical" means any drug that emits ionizing radiation and includes:

Any nonradioactive reagent kit, nuclide generator, or ancillary drug intended to be used in the preparation of any radiopharmaceutical but does not include drugs such as carbon-containing compounds or potassium-containing salts, that contain trace quantities of naturally occurring radionuclides; and

Any biological product that is labeled with a radionuclide or intended to be labeled with a radionuclide.

"Radiopharmaceutical quality assurance" means the performance of appropriate chemical, biological, and physical tests on potential radiopharmaceuticals and the interpretation of the resulting data to determine the suitability of the potential radiopharmaceuticals for use in humans and animals. Radiopharmaceutical quality assurance includes internal test assessment, authentication of product history, and the keeping of proper records.

"Radiopharmaceutical services" means, the procuring, storing, handling, compounding, preparing, labeling, quality assurance testing, dispensing, distributing, transferring, recordkeeping, and disposing of radiochemicals, radiopharmaceuticals, and ancillary drugs, and includes quality assurance procedures, radiological health and safety procedures, consulting activities associated with the use of radiopharmaceuticals, and any other activities required for the provision of pharmaceutical care.

"Red C stamp" means a device used with red ink to make an invoice of a controlled substance in schedules III through V readily retrievable, as required by state and federal rules, by imprinting the invoice with a red letter C at least 1 inch high.

"Remodel" means to structurally alter the pharmacy area or location.

"Remote drug storage area" means an area that is outside the premises of the pharmacy, used for the storage of drugs, locked to deny access by unauthorized persons, and secured against the use of force.

"Resident" means a person admitted to and residing in a long term care facility.

"Score transfer" means the process that enables an applicant to take the NAPLEX in a jurisdiction and be eligible for licensure by examination in other jurisdictions.

"Sterile pharmaceutical product" means a dosage form free from living micro-organisms.

"Strength" means:

The concentration of the drug substance (for example, w/w, w/v, or unit dose/volume basis) and/or

The potency, that is, the therapeutic activity of the drug substance as indicated by bioavailability tests or by controlled clinical data (expressed, for example, in terms of unity by reference to a standard).

"Supervision" means the pharmacist shall be present, assume legal responsibility, and have personal oversight of activities relating to the acquisition, preparation, distribution, and sale

of prescription medications by pharmacy interns or supportive personnel.

"Supplying" means selling, transferring, or delivering to a patient or a patient's agent one or more doses of:

A nonprescription drug in the original container of a manufacturer for subsequent use by the patient, or

A compressed medical gas in the original container of a manufacturer or compressed medical gas distributor for subsequent use by the patient.

"Supportive Personnel" means an individual trained to perform activities related to the preparation and distribution of prescription medications, under the supervision of a pharmacist and consistent with policy and procedures as required in R4-23-403.

"Transfill" means the manufacturing process by which one or more compressed medical gases are transferred from a bulk container or containers to a properly labeled container or containers for subsequent distribution or supply.

"Wholesale distribution" means distribution of drugs to persons other than a consumer or patient, but does not include:

The sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons. For purposes of this section, "emergency medical reasons" includes transfer of prescription drugs by a community or hospital pharmacy to another community or hospital pharmacy to alleviate a temporary shortage;

The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;

The distribution of drug samples by manufacturers' representatives or distributors' representatives; or

The sale, purchase, or trade of blood and blood components intended for transfusion.

"Wholesale distributor" means any one engaged in wholesale distribution of drugs, including, but not limited to manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies that conduct wholesale distributions in the amount of at least five percent of gross sales.

ARTICLE 4. PROFESSIONAL PRACTICES

R4-23-402. Pharmacist, Graduate Intern, and Pharmacy Intern

A. The following professional practices in ~~directly~~ dispensing a prescription medication from a prescription order shall be performed by a pharmacist or a graduate intern or pharmacy intern under the supervision of a pharmacist:

1. Receive~~Receipt of~~ reduce to written form, and manually initial oral prescription orders~~.~~;
2. Obtain and record the name of the individual who communicates an oral prescription order;
3. Obtain and record, or assume responsibility to obtain and record, in the patient profile the following information:
   a. Name, address, telephone number, date of birth (or age), and gender;
   b. Individual history including known diseases and medical conditions, known drug allergies or drug reactions, and if available a comprehensive list of medications currently taken and relevant medical devices currently used;
   c. Pharmacist's comments relevant to the individual's drug therapy, including other information specific to the patient or drug;
4. ~~2.~~ Verify~~Verification of~~ legalities and pharmaceutical feasibility of dispensing the drug, including allergies, incompatibilities, unusual quantities of dangerous drugs or narcotics, signature of medical practitioner, and frequency of refills~~.~~;
5. ~~3.~~ Verify~~Verification~~ that dosage is within proper limits~~.~~;
6. ~~4.~~ Interpret~~ing~~ the prescription order~~.~~;
7. ~~5.~~ Compound~~ing~~, mix~~ing~~, combine~~combining~~, or otherwise prepare~~preparing~~ and package~~packaging~~ the prescription medication needed to dispense individual prescription orders, with the exception of prepackaging procedures delineated in ~~the following paragraph (6)~~subsection (A)(8)~~.~~;
8. ~~6.~~ Prepackage~~Prepackaging~~ or supervise~~supervising~~ the prepackaging of drugs~~;~~, provided, however, that a~~the~~ pharmacist shall verify the drug to be prepackaged, decide the wording and requirements ~~to be~~ placed on the label, and check the completed prepackaging procedure and product~~.~~;
9. ~~7.~~ Check~~ing~~ the label to ensure~~see~~ that it communicates the prescriber's directions precisely~~.~~;
10. ~~8.~~ Record~~ing~~, or assume~~assuming~~ responsibility to ~~for the~~ record~~ing, of~~ the prescription serial number and ~~the~~ date dispensed on the ~~front of an~~ original prescription order.
11. ~~9.~~ Obtain~~ing~~, or assume~~assuming~~ responsibility to ~~for the~~ obtain~~ing, of~~ permission to refill prescription orders and record~~ing~~, or assume~~assuming~~ responsibility to ~~for the~~ record~~ing, of~~ the date dispensed, ~~and~~ quantity dispensed, and name of medical practitioner or medical practitioner's agent who communicates permission to refill the prescription order ~~on the prescription order.~~;
12. ~~10.~~ Make~~Making the~~ a final check on the completed prescription medication and manually initial the finished label;
13. Reduce to written or printed form or assume responsibility to reduce to written or printed form a new prescription order received by facsimile, computer modem, or other means of communication;
14. ~~11.~~ Verify~~Transcribing~~ and manually initial a new ~~verbal~~ prescription order~~.~~ received by facsimile, computer modem, or other means of communication;
15. ~~12.~~ Record~~ing~~ on the original prescription order the name or initials of the pharmacist, graduate intern, or pharmacy intern who originally ~~initially~~ dispense~~sd~~ the order~~.~~; and
16. ~~13.~~ Record~~ing~~ on the original prescription order the name or initials of the pharmacist, graduate intern, or pharmacy intern who dispense~~sd~~ each refill.

B. Only a~~The~~ pharmacist, graduate intern, or pharmacy intern shall ~~personally~~ provide oral consultation about the prescription medication ~~oral communication, which shall include directions for use, name of prescribed medication, and any special instructions, precautions or storage requirements,~~ to the patient or patient's agent in all outpatient settings, including ~~the provision of~~a hospital discharge, ~~medications~~ whenever ~~any of~~ the following occurs:

1. The ~~prescribed~~prescription medication has not been previously dispensed to the patient;
2. ~~or~~ A new prescription number is assigned to a previously dispensed prescription medication;

~~2~~3. The prescription medication ~~drug~~ has not ~~previously~~ been previously dispensed to the patient in the same strength~~,~~ or dosage form~~,~~ or with the same directions;

~~3~~4. ~~In the~~ The pharmacist, through the exercise of professional judgment, ~~of the pharmacist, it~~determines that oral consultation is ~~deemed~~ warranted; or

~~4~~5. ~~Upon request of~~ The patient or patient's agent requests oral consultation.

C. Oral consultation shall include:

1. The name, strength, and dosage form of the prescription medication or device;
2. The directions for use;
3. The route of administration; and
4. Special instructions, precautions, or storage requirements.

D. The pharmacist, through the exercise of professional judgment, may provide oral consultation that includes:

1. Common severe adverse effects, interactions or therapeutic contraindications, and the action required if they occur;
2. Techniques of self-monitoring drug therapy;
3. The duration of the drug therapy;
4. Prescription refill information; and
5. Action to be taken if a dose is missed.

E. Nothing in subsection (B) shall be construed as requiring a pharmacist, graduate intern, or pharmacy intern to provide oral consultation when a patient or patient's agent refuses the consultation. Only a pharmacist, graduate intern, or pharmacy intern shall accept a refusal for consultation. A pharmacist, graduate intern, or pharmacy intern shall document, or assume responsibility to document, a refusal for consultation on the original prescription order or by alternative methods approved by the Board or its designee.

~~C~~.F. When a prescriptions is~~are~~ delivered to the patient or patient's agent outside ~~of~~ the immediate area of the pharmacy and a pharmacist is not present, the prescription shall be accompanied by written or printed patient medication information that, in addition to the requirements in subsection (C), includes: ~~sufficient to satisfy the requirements in R4-23-402(B). This information shall include a telephone number for consultation with a pharmacist.~~

1. Approved indication for the prescription medication;
2. Possible adverse reactions;
3. Drug-drug, food-drug or disease-drug interactions;
4. Missed dose information; and
5. Telephone number of the dispensing pharmacy.

~~D~~.G. Prescription medications or devices ~~Prescriptions or drug orders~~, delivered to patients at locations where licensed health care professionals are responsible for ~~patient care including~~ administering prescription medications to patients, are exempt from the requirement of ~~R4-23-402~~subsection (B).

~~E. Prescriptions or drug orders, delivered to patients or patient's agents who desire to waive this oral communication with the pharmacist or pharmacist intern, are exempt from the requirement of R4-23-402(B), providing that documentation to this effect is placed on the original prescription.~~

~~F~~.H. A pharmacists, graduate intern, ~~and~~or pharmacy interns shall wear a badges indicating ~~their~~ name and title while on duty.

~~G~~.I. Nothing in this rule shall prevent hospital pharmacists from accepting prescription orders in accordance with regulations pertaining specifically to hospital pharmacies.

NOTICE OF PROPOSED RULEMAKING

TITLE 7. EDUCATION

CHAPTER 1. STATE BOARD OF DIRECTORS FOR COMMUNITY COLLEGES OF ARIZONA

PREAMBLE

1. **Sections Affected** — **Rulemaking Action**

R7-1-701	New Section
R7-1-702	Renumber
R7-1-702	Amend
R7-1-703	Renumber
R7-1-703	Amend
R7-1-704	New Section
R7-1-710	Amend

2. **The specific authority for the rulemaking, including both the authorizing statute and the statutes the rules are implementing:**

Authorizing statute: A.R.S. § 15-1425(6)

Implementing statute: A.R.S. § 15-1426(6)

3. **The name and address of agency personnel with whom persons may communicate regarding the rulemaking:**

Name: Thomas J. Saad

Address: State Board of Directors for Community Colleges
3225 North Central Avenue, Suite 1220
Phoenix, Arizona 85308

Telephone: (602) 255-4037

Fax: (602) 279-3464

4. **An explanation of the rule, including the agency's reasons for initiating the rule:**

R7-1-701 *Definitions Regarding Instruction.* Definition of words and phrases concerning the rules within the article. The new section represents the collection of all definitions in one place. Definitions are currently scattered throughout the article.

R7-1-702 *General Program and Course Standards.* Standards must be revised to conform to recommendations of the report of the "Task Force on Transfer Articulation" as adopted by the Board of Regents and the State Board.

R7-1-703 *Procedure for Submitting Curriculum to State Board for Approval.* The amendments are technical in nature. The rule is renumbered to conform. Definitions have been removed from this section and included in the new section R7-1-701.

R7-1-704 *Course Numbering.* Course numbering is currently specified outside of formal rules. It should be included within the rules process and format.

R7-1-710 *Open Entry, Open Exit Courses.* Amendments are technical in nature--renumbering to conform.

5. **A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:**

The amendments and new sections proposed will not diminish authority of the community colleges under the State Board's jurisdiction.

6. **The preliminary summary of the economic, small business, and consumer impact:**

Proposed amendments and new rules will not have any impact on small businesses or the community colleges.

The nature of proposed changes will promote the enhanced quality of educational services to students, without any adverse impacts to the community colleges.

7. **The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:**

Name:	Thomas J. Saad
Address:	State Board of Directors for Community Colleges 3225 North Central Avenue, Suite 1220 Phoenix, Arizona 85308
Telephone:	(602) 255-4037
Fax:	(602) 279-3464

8. **The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:**

Date:	April 17, 1998
Time:	1 p.m.
Location:	2323 West 14th Street Tempe, Arizona
Nature:	Public Hearing

9. **Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:**

None.

10. **Incorporations by reference and their location in the rules:**

American Council on Education's *"A Guide to Educational Credit by Examination, 4th Edition"*.

Found in R7-1-702(C)(1).

American Council on Education's *"The 1996 Guide to the Evaluation of Educational Experiences in the Armed Forces"*. Found in R7-1-702(C)(2).

American Council of Education's *"National Guide to Educational Credit for Training Programs, 1996 Edition"*.

Found in R7-1-702(C)(2).

11. **The full text of the rules follows:**

TITLE 7. EDUCATION

CHAPTER 1. STATE BOARD OF DIRECTORS FOR COMMUNITY COLLEGES OF ARIZONA

ARTICLE 7. INSTRUCTION, FACULTY AND STAFF

Section

R7-1-701. Definitions Regarding Instruction

~~R7-1-701.~~R7-1-702.General Program and Course Standards

~~R7-1-702.~~R7-1-703.Procedure for Submitting Curriculum to State Board for Approval

R7-1-704. Course Numbering
R7-1-710. Open Entry, Open Exit Courses

ARTICLE 7. INSTRUCTION, FACULTY AND STAFF

R7-1-701. Definitions Regarding Instruction

In this chapter, unless the context otherwise requires:

1. "Associate degree" means a credential awarded for completing a curriculum requiring a minimum of 60 semester hours of course credits.
2. "Certificate" or "certificate of completion" means a credential awarded for completing a curriculum requiring less than 60 semester hours of course credits.
3. "Skill center certificate of completion" means a credential awarded for completing a skill center vocational training program.
4. "Credit course" means a course which provides college level rigor and complexity and meets the criteria for credit courses provided by R7-1-702(B).
5. "Credit hour" means semester hour.
6. "Competency-based course" means a course in which student performance is evaluated by mastery of predefined competencies, rather than by the amount of time spent in class.
7. "Curriculum" means a program of study containing a planned sequence of courses leading to a degree or certificate.
8. "Baccalaureate parallel curriculum" means a program of study designed to provide the first two years of a baccalaureate degree program for transfer to a four-year college or university.
9. "General studies curriculum" means a program of study designed to address student needs other than those included in the baccalaureate parallel curriculum or occupationally oriented curriculum.
10. "Occupationally oriented curriculum" means a program of study designed to prepare a student for employment or advancement in the program field.
11. "Developmental education credit course" means a course designed to provide the foundation for retention and learning success of academically underprepared students.
12. "General education curriculum" means a program of study designed to provide a structure in which the accumulation of knowledge and practice of disciplined, independent thinking can grow into comprehensive understanding and reasoned value.
13. "General education course" means a course designed to broaden the student's knowledge and awareness in each of the principal areas of human knowledge.
14. "Arizona General Education Curriculum (AGEC)" means a group of courses or other educational experiences approved as satisfying the general education requirements of a baccalaureate parallel curriculum articulated under the provisions of the Report of the Transfer Articulation Task Force dated October 30, 1996.
15. "Independent study" means learning method in which students, without formal class attendance requirements, consult periodically with one or more certified instructors for direction, assistance, and work toward the completion of competencies.
16. "Instructional hour" means the time an instructor spends in delivering instruction or supervising learning activities. It is based on a fifty (50) minute period in a traditional 16-week semester.
17. "Laboratory hour" means the time during which students are involved in learning activities, such as experiments or performance of skill, under the supervision of an instructor. It is based on a fifty (50) minute period in a traditional 16-week semester.
18. "Open entry, open exit course" means acourses that may commence any time during the fiscal year and is characterized by students entering at various times and exiting upon mastery of specified competencies. Open entry, open exit courses feature individualized instruction and are competency-based.
19. "Semester" means the community college instructional term that that is traditionally sixteen weeks in length.
20. "Semester credit hour" means the value of an academic credit, the standards for which may be based on the length of the course or on the competencies mastered.
21. "Short-term course" means a course that is not in session on the forty-fifth day of the fall or spring semester and which commences at various times during the fiscal year and which is offered over a period of less than sixteen weeks.
22. "Skill center vocational training program" means a program offered by a community college district under the provisions of A.R.S. 15-1466 that is performance based, features individualized instruction and includes the knowledge, skills, and attitudes needed for successful job entry or advancement as verified by advisory groups.
23. "Skill center program completer" means a student who completes a planned sequence of instruction, services, activities or experiences designed to meet the individual's occupational objective as determined by an individualized vocational education plan (IVEP)/ employability development plan (EDP). This student shall have met all requirements of the institution for program completion to be eligible for a skill center certificate of completion.
24. "Skill center full-time student equivalent" (FTSE) is equal to six hundred forty (640) clock hours. Only clock hours generated by program completers shall qualify for skill center state aid funding. Hours granted by examination or evaluation for previously mastered competencies shall not be eligible for state aid funding.
25. "State Board" means the State Board of Directors for Community Colleges of Arizona.
26. "Adverse impact" means an undesirable effect of a proposed curriculum on a viable existing program or service of another Arizona community college district that, in the judgment of the State Board, is unacceptable when weighed against the expected benefit of the proposed curriculum. Such undesirable effects may include effects on the enrollment of an established program, placement of graduates of an established program, funding of an established program or service, or other similar considerations.

~~R7-1-701.~~R7-1-702. General Program and Course Standards

A. Each community college under the jurisdiction of the State Board shall offer a program that meets the educational needs of the population that it serves. The State Board establishes the following curricular standards and requires each community college district to implement them.
   1. Occupationally oriented curricula – Each college district shall offer occupationally oriented programs designed to lead to an associate degree. The district may also offer programs of shorter duration designed to lead to

employment when an associate degree is not appropriate but where a certificate of completion may be issued.

2. Baccalaureate parallel curricula – Each district shall offer baccalaureate parallel curricula of such quality and content that will permit transfer into third-year college classes in baccalaureate degree programs.
   a. Each district shall offer one or more curricula for each of the following baccalaureate parallel associate degrees meeting the criteria for the respective degree contained in the Report of the Task Force on Transfer Articulation dated October 30, 1996, which was approved by the Arizona Board of Regents on November 1, 1996, and the State Board on November 15, 1996, and accepted by the Joint Legislative Budget Committee on December 4, 1996.
      i. The Associate in Arts degree, which includes a general education component of at least 35 semester credit hours and, for the General Requirements version of the degree, includes fourth semester proficiency in a non-English language (not a computer language).
      ii. The Associate in Business degree, which includes a general education component of at least 35 semester credit hours
      iii. The Associate in Science degree, which includes advanced mathematics requirements and a general education component of at least 35 semester credit hours.
   b. Each district may offer one or more baccalaureate parallel associate degree curriculum which has been specially articulated with one or more university to meet special transfer needs as described as having exceptional requirements in the Report of the Task Force on Transfer Articulation cited in Section (A)(2)(a), above.
3. Special programs – Each district shall offer such full-time and part-time day or evening programs as required by particular educational and economic needs of the community and which can be provided economically. Programs may include, but are not limited to, community service programs, continuing or adult education, and developmental programs.
4. Academic and Occupational testing and guidance programs. – Each district shall provide services for academic and occupational testing, guidance, and individual development.
5. Specialized educational programs. – The State Board may authorize specialized educational programs (see rule R7-1-301, subsection (C)).

B. Courses offered for credit shall satisfy one or more of the purposes under Section (B)(1), below, and shall meet all requirements set forth in Section (B)(2), below.

1. Purpose. Credit courses shall satisfy one or more of the following purposes.
   a. Qualify students for a community college certificate or degree.
   b. Be acceptable for transfer to a regionally accredited public or private college or university.
   c. Prepare students with skills to seek entry level jobs in the field of specialization.
   d. Improve the student's job skills or prepare the student for promotion in fields of employment.
   e. Provide skills necessary for success in other college courses.
   f. Meet other needs in the community through continuing education, lifelong learning, physical health and wellness.
2. Requirements. A credit course must satisfy each of the following criteria.
   a. A formal course outline, which defines the objectives, ~~and~~ content of the course, and pre-requisites for the course shall be on file and available for audit.
   b. Students performance shall be evaluated and ~~given~~ a grade based on ~~their~~ mastery of the objectives and content of the course shall be given.
   c. Faculty teaching the course shall hold a valid certificate, issued by the State Board, to teach in the subject of the course.
   d. The credits awarded for completion of the course shall be based upon the effort required of, and the competencies to be gained by, the students in accordance with policies adopted by the District Governing Board and approved by the State Board.
   e. Before enrollment in the course, students shall have achieved prerequisite competencies defined in the syllabus.
   f. The course shall have been developed using the District's formal curriculum review procedure that shall include at least the following features:
      i. The course shall have been reviewed by the college's curriculum committee and recommended by the college administration.
      ii. The course shall have been reviewed and approved by the District Governing Board as adhering to the standards set forth in this Section.
   g. The course shall have an evaluation component. The results of these evaluations shall be used for the purposes of formative and summative evaluation by the institution.

C. Students may receive credit through a variety of other means described below.

1. National Standardized Examinations. A District Governing Board may adopt a policy to provide that credit may be awarded for satisfactory scores on national standardized examinations listed in the American Council on Education's "A Guide to Educational Credit by Examination, 4th Edition". Incorporated herein by reference and on file with the offices of the Secretary of State and the Board of Directors for Community Colleges of Arizona The College Level Examination Program (CLEP) is an example of such an examination. The district policy for granting such credit shall be printed in the college catalog along with a statement indicating that acceptance of such credits upon transfer may be treated differently by the institution to which a student transfers.
2. Credit by Evaluation. A District Governing Board may adopt a policy to provide that credit may be awarded by evaluation of military training and experiences as well as non-collegiate sponsored training programs listed in the American Council on Education's "The 1996 Guide to the Evaluation of Educational Experiences in the Armed Services" and the American Council on Education's "National Guide to Educational Credit for Training Programs, 1996 Edition," ~~I~~ incorporated herein by reference and on file with the offices of the Secretary of State and the Board of Directors for Community Col-

leges of Arizona. The district policy for granting such credit shall be printed in the college catalog along with a statement indicating that acceptance of such credits upon transfer may be treated differently by the institution to which a student transfers.

3. Departmental Credit by Examination. A District Governing Board may adopt a policy to provide that credit may be awarded for satisfactory scores on departmental examinations. The district policy for granting such credit shall be printed in the college catalog along with a statement indicating that acceptance of such credits upon transfer may be treated differently by the institution to which a student transfers.
4. Departmental Credit by Evaluation. A District Governing Board may adopt a policy to provide that credit may be awarded by evaluation of prior learning. The district policy for granting such credit shall be printed in the college catalog along with a statement indicating that acceptance of such credits upon transfer may be treated differently by the institution to which a student transfers.
5. Transfer Courses. A District Governing Board may adopt a policy to provide that credit may be awarded for courses satisfactorily completed at a regionally accredited post-secondary institution upon receipt of official student transcripts. Transfer credit from non-accredited post-secondary institutions may also be accepted if such credits represent equivalent or higher level work at the receiving institution.
6. Articulated Equivalent Course. A District Governing Board may adopt a policy to provide that credit may be awarded for courses satisfactorily completed by students enrolled in secondary institutions provided that:
   a. The district has adopted guidelines for granting articulation credit that defines the curricular areas included in the policy and written documentation is provided by the secondary institution that identifies the previously mastered skills or competencies as certified by the School Superintendent or designee.
   b. The secondary course competencies are equivalent to or more advanced than the same course(s) at the community college.
   c. The district policy for granting such credit is printed in the college catalog together with a statement indicating that acceptance of such credits upon transfer may be treated differently by the institution to which a student transfers.

D. The District Governing Board shall adopt and obtain the State Board's approval for curriculum standards and guidelines that incorporate the course criteria contained in paragraph B.2.

E. Community College districts shall maintain documentation of compliance with the provisions of Sections A through C for review by the State Board or the auditor general.

F. Non-credit courses, cultural and community services, economic development services not qualifying as credit courses that may be developed by the District, and the support of community cultural development, shall be the financial responsibility of the District Governing Board.

~~R7-1-702.~~ R7-1-703. Procedure for Submitting Curriculum to State Board for Approval

~~A. The following definitions apply to the terms used in this section.~~

~~1. "Curriculum" means a program of study containing a planned sequence of courses leading to a degree or certificate.~~
~~2. "Baccalaureate Parallel Curriculum" means a program of study designed to transfer to a four-year college or university.~~
~~3. "General Studies Curriculum" means a program of study designed to address student needs other than those included in the baccalaureate parallel curriculum or occupationally oriented curriculum.~~
~~4. "Occupationally Oriented Curriculum" means a program of study designed to prepare a student for employment or advancement in the program field.~~
~~5. "State Board" means the State Board of Directors for Community Colleges of Arizona.~~
~~6. "Adverse Impact" means an undesirable effect of a proposed curriculum on a viable existing program or service of another Arizona community college district that, in the judgment of the State Board, is unacceptable when weighed against the expected benefit of the proposed curriculum. Such undesirable effects may include effects on the enrollment of an established program, placement of graduates of an established program, funding of an established program or service, or other similar considerations.~~

~~B~~A. Each degree or certificate curriculum offered by a community college district shall have been approved by the State Board as required by A.R.S. § 15-1425.6. The best interest of the state shall be determined by the application of the following three primary criteria:

1. The curriculum shall meet an identified community, state, regional, or national need defined by the local district curriculum review process.
2. The curriculum shall have been developed and approved at the community college district level following a procedure that meets at least the minimum standards specified in subsection (C);
3. The curriculum will not have an adverse impact on the existing programs and services of another Arizona community college district.

~~C~~B. In its request for curriculum approval, the district shall demonstrate that it has used a curriculum review process that includes, as a minimum, the following elements:

1. An analysis shall have been conducted that establishes the need for the curriculum.
2. For occupationally oriented curricula, the program design shall be based upon the knowledge and skills required for employment or advancement in the program field as determined by a systematic study involving potential employers and others expert in the field.
3. For baccalaureate parallel curricula, the program shall be designed to enable a graduate of the program to satisfy Arizona public university lower-division general education requirements and to transfer to a public Arizona university with upper division status.
4. A resource study shall have been conducted that demonstrates the community college district will have the financial resources, physical facilities, and qualified faculty to establish and sustain the curriculum.
5. A review within the community college district shall have been conducted to assure that all affected entities within the district have been provided an opportunity to comment, following the district's normal internal approval procedure.

6. An analysis of the impact of the curriculum upon other districts and the attempts made by the district to resolve any concerns expressed by the staff of the State Board or other districts.
7. The district governing board shall have approved the curriculum and recommend its approval by the State Board.

~~D~~C. At the conclusion of the analysis described in subsection (C)(1), above, the community college district shall notify the other community college districts and the staff of the State Board of its intent to consider the development of a new curriculum. The State Board and community college districts shall notify the proposing district of any concerns within sixty (60) days of such notice.

~~E~~D. The State Board approval process shall consist of the following steps.

1. Upon receipt of a curriculum approval request, the State Board shall notify all other Arizona community college districts of the pending request. This notice shall be made at least thirty (30) days before the date of the State Board meeting at which the request will be considered.
2. Any district that has notified the State Board and the initiating district of a concern, in accordance with subsection (E)(1), shall be provided an opportunity to comment on its concern in an open meeting of the State Board. The initiating district shall have an opportunity for rebuttal prior to a final decision by the State Board.
3. The State Board staff shall review the curriculum approval request and submit to the State Board a recommendation that the Board find that the curriculum review criteria described in subsection (C) have been satisfied.
4. The State Board shall consider the request for curriculum approval in terms of the satisfactory application of its curriculum review criteria and the impact of the program on other Arizona community college districts.

~~F~~E. Notwithstanding the procedures described previously in this section, the State Board may grant temporary interim approval for initiation of a curriculum under the following conditions:

1. The curriculum meets each of the following criteria:
   a. The curriculum is in support of economic development or job training for a new or established Arizona employer or employers.
   b. The curriculum is no more than forty (40) semester credit hours in length.
   c. The State Board has determined that it is unlikely that the curriculum will have an adverse impact on another Arizona community college district during the limited approval period.
2. The temporary interim approval shall be for no more than one year, during which time the full curriculum approval process must have been completed if the curriculum is to be continued.
3. Temporary interim approval shall not be a justification for regular curriculum approval.

R7-1-704. Course Numbering

Each community college credit course shall be designated by three alphabetical characters identifying the subject area and three numerical characters. The course numbering shall follow the standards defined below:

1. Freshman level standard credit courses shall be numbered between 100 and 199;
2. Sophomore level standard credit courses shall be numbered between 200 and 299;
3. Developmental credit courses shall be numbered 0-99; and
4. Non-credit courses shall not be numbered 0-299.

R7-1-710. Open Entry, Open Exit Courses

A. All open entry, open exit courses offered by a community college district shall comply with the provisions of R7-1-70~~1~~2 (B).
B. Each open entry, open exit course shall have clearly defined and measurable competencies.
C. The State Board may periodically review all open entry, open exit courses pursuant to (A) and (B) of this rule.